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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/669,768	09/24/2003	Yuqiao Shen	ONYX1047-DIV	8135

37499 7590 03/02/2006

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EXAMINER	
MARVICH, MARIA	

ART UNIT	PAPER NUMBER
1633	

DATE MAILED: 03/02/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/669,768	SHEN ET AL.	
	Examiner	Art Unit	
	Maria B. Marvich, PhD	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 September 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *6-19* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *6-19* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

This restriction is in response to a preliminary amendment filed 9/24/03. This restriction requirement replaces in total the restriction requirement mailed 2/10/06. Claims 1-5 and 20-22 have been canceled. Claims 6-19 are pending in this application and subject to restriction.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 9 and 10, drawn to a polynucleotide comprising an adenovirus with a single mutation in the E1B-55K gene that is Onxy 051, classified in class 424, subclass 93.2.

II. Claims 9 and 10, drawn to a polynucleotide comprising an adenovirus with a single mutation in the E1B-55K gene that is Onxy 053, classified in class 424, subclass 93.2.

III. Claims 6 and 7, drawn to a an isolated E1B-55K protein with a single mutation at position 240, classified in class 530, subclass 350.

IV. Claim 6 and 8, drawn to a an isolated E1B-55K protein with a single mutation at position 240, classified in class 530, subclass 350.

V. Claim 11, 12, 14-16, 18 and 19, drawn to a method of treating cancer in a patient by administration of an adenovirus comprising a single mutation in the E1B-55K protein that is Onyx 051, classified in class 514, subclass 44.

VI. Claim 11, 13, 14, 15, and 17-19, drawn to a method of treating cancer in a patient by administration of an adenovirus comprising a single mutation in the E1B-55K protein that is Onyx 053, classified in class 514, subclass 44.

The inventions are distinct each from the other because of the following reasons:

The polypeptide of Groups III and IV and adenovirus or polynucleotide of Groups I and II is patentably distinct inventions for the following reasons. Polypeptides, which are composed of amino acids, and polynucleotides, which are composed of purine and pyrimidine units, are structurally distinct molecules; any relationship between a polynucleotide and polypeptide is dependent upon the information provided by the nucleic acid sequence open reading frame as it corresponds to the primary amino acid sequence of the encoded polypeptide. In the present claims, the polynucleotide of Groups I and II does not necessarily encode the polypeptides of Groups III and IV. Specifically, the polynucleotides of Groups I and II comprise the entire adenovirus genome while the polypeptides of Groups III and IV is a single protein within the genome. Furthermore, the information provided by the polynucleotide of Group I and II can be used to make materially different polypeptides than that of Group III-IV. In addition, while a polypeptide of Group III or IV can made by methods using some, but not all, of the polynucleotides that fall within the scope of Groups I and II, it can also be recovered from a natural source using by biochemical means. For instance, the polypeptide can be isolated using affinity chromatography. For these reasons, the inventions of Groups I-IV are patentably distinct.

Furthermore, searching the inventions of Groups I-II and III-IV together would impose a serious search burden. In the instant case, the search of the polypeptides and the polynucleotides are not coextensive. The inventions of Groups I-II and III-IV have a separate status in the art as shown by their different classifications. The scope of polynucleotides as claimed extend beyond a polynucleotide that encodes the claimed polypeptides as explained above; furthermore, a search of adenovirus or polynucleotide of the adenovirus is not the same search for a polypeptide encoded by the adenovirus and as such the searches are not overlapping. As such, it would be burdensome to search the inventions of Groups I-II and III-IV together.

The adenoviruses and polynucleotides of Group I and II are patentably distinct as they are structurally and functionally distinct. As well, the polypeptides of Groups III and IV are patentably distinct as they are structurally and functionally distinct. The polynucleotide of Group I comprises coding sequences for the polypeptide of Group III in which there is a mutation in amino acid 240 while the polynucleotide of Group II comprises coding sequences for the polypeptide of Group IV in which there is a mutation in amino acid 260. By the distinct mutations, a structurally distinct molecule is generated. The distinct structure is responsible for functions that are also distinct. For example, the mutation in amino acid 240 restored can restore the wild-type capacity of ONXY-015 while the mutation in 260 only does so partially. As well, resulting viruses have distinct replication functions in cold-sensitivity assays (see page 22). Hence, the inventions of Group I and II are patentably distinct.

Inventions I-II are related as product and process of use with the inventions of Groups V and VI. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially

different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the polynucleotide can be used *in vitro* to analyze E1B function.

Searching the inventions of Groups I-II and V-VI together would impose serious search burden. The inventions of Groups I-II versus Groups V-VI have a separate status in the art as shown by their different classifications. Moreover, in the instant case, the search for the adenovirus or polynucleotides and the method of treating cancer using the adenovirus or polynucleotide are not coextensive. Prior art, which teaches a adenovirus or polynucleotide with a mutation in the E1B region, would not necessarily be applicable to the method of using the product. Moreover, even if the product were known, the method of treatment, which uses the product, may be novel and unobvious in view of the preamble or active steps.

Inventions III-IV and either V or VI are unrelated because the products of Group III and IV are not used or otherwise involved in the process of Group V or VI.

Inventions V, and VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). The instant specification does not disclose that these methods would be used together. The method of treatment using Onyx-051 uses a virus or polynucleotide that is distinct from a method of treatment using Pnyx-053. Furthermore, the method of action and of assaying for function are distinct given the differences functionally in the two viruses. Therefore, each method is divergent in materials and steps. For these reasons the Inventions IV, V and VI are patentably distinct.

Furthermore, the distinct steps and products require separate and distinct searches. The inventions of Groups V and VI have a separate status in the art as shown by their different classifications. As such, it would be burdensome to search the inventions of Groups V and VI together.

Because these inventions are distinct for the reasons given above, have acquired a separate status in the art as shown by their different classification, and the search required for each group is not required for the other groups because each group requires a different non-patent literature search due to each group comprising different products and/or method steps, restriction for examination purposes as indicated is proper.

Claim 9 links the inventions of Groups I-II. Claim 6 links the inventions of Groups III-IV. Claims 11 and 14 link the inventions of Groups V and VI. The restriction requirement between the linked inventions is subject to the nonallowance of the linking claims. Upon the allowance of the linking claims, the restriction requirement as to the linked inventions shall be withdrawn and any claim depending from or otherwise including all the limitations of the allowable linking claims will be entitled to examination in the instant application. Applicants are advised that if any such claim depending from or including all the limitations of the allowable linking claims is presented in the continuation or divisional application, the claims of the continuation of divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. See MPEP 804.01.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provision of MPEP 821.04. Process claims that depend for or otherwise include all the limitations of the patentable produce will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendment submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirements for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 USC 101, 101, 103 and 112. Until an elected product claim is found allowable, an otherwise proper restriction between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claim in light of *In re Ochiai, In re Brouwer* and 35 USC 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 USC 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP 804.01.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maria B. Marvich, PhD whose telephone number is (571)-272-0774. The examiner can normally be reached on M-F (6:30-3:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David Nguyen, PhD can be reached on (571)-272-0731. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Maria B Marvich, PhD
Examiner
Art Unit 1633

March 1, 2006